

## REMARKS

Claims 1, 2 and 5-7 are pending in the present application. Claims 1 and 6 have been amended to clarify that the recited teas are not fermented teas, such as black tea. Although the specification does not explicitly use the word “unfermented,” M.P.E.P. 2163 provides that the written description can be met “even if every nuance of the claims is not explicitly described in the specification,” and that “the description need not be in *ipsis verbis* [i.e., ‘in the same words’] to be sufficient.” Rather, it is sufficient that “each claim limitation must be expressly, implicitly, or inherently supported by the originally filed disclosure.” *Id. at subpart (II)I(A)(3).*

Here, the limitation “unfermented” is inherently supported by the original disclosure because one of ordinary skill in the art would recognize that the teas disclosed in the present application are necessarily unfermented teas. In order for a disclosure to be an “inherent” disclosure of a characteristic, it must be shown that “the allegedly inherent characteristic necessarily flows from the teachings . . .” M.P.E.P. 2112(IV) (emphasis in original).

The present application contains a disclosure showing that the teas described must necessarily be unfermented teas. In particular, the specification discloses that O-methylated catechins are extracted from specific types of tea in high amounts, up to 30 mg per 100 ml of beverage. *See, e.g., Specification at [0047]-[0048].* By contrast, deeply fermented teas, such as black tea, contain only insignificant levels of O-methylated catechins, such as EGCG3”Me. *See Yamamoto et al., “The Change of Epigallocatechin-3-O-(3-O-methyl) gallate Content in Tea of Different Varieties, Tea Seasons of Crop and Processing Method,” in Journal of the Japanese Society for Food Science and Technology, 48:64-68 (2001).* Accordingly, one of ordinary skill in the art at the time of the invention would recognize that fermented teas could not contain the amount of O-methylated catechins disclosed in the present application. Thus, the teas disclosed in the present application must inherently be unfermented teas, as fermented teas could not possibly have led to the levels of O-methylated catechins disclosed. Thus, no new matter has been added. Reconsideration and withdrawal of the present rejections in view of the comments presented herein are respectfully requested.

### Rejection under 35 U.S.C. § 103(a)

Claims 1, 2 and 5-7 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Zeyuan *et al.* (*J. Agric. Food Chem.* 46:3875-3878, 1998) in view of Suzuki *et al.* (*J. Agric. Food Chem.* 48:5649-5653, 2000) and in further view of Iwasaki *et al.* (US

7,014,876). To support a *prima facie* case of obviousness the Examiner must consider “[a]ll words in a claim . . . in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); *see also* M.P.E.P. § 2143.03. Furthermore, there must be a “clear articulation of the reason(s) why the claimed invention would have been obvious.” M.P.E.P. § 2142. In the present case, no *prima facie* the cited combination of references would not lead one having ordinary skill in the art to produce the claimed invention.

The pending claims recite a method of reduction of triglyceride levels by administering a functional beverage (claim 1) or composition (claim 6) comprising the recited methylated catechins and extracted from the recited list of unfermented tea leaves. The present invention relates, in part, to Applicants’ discovery that the recited methylated catechins are unexpectedly much better than non-methylated catechins at reducing triglyceride (TG) levels. Based on this unexpected discovery, the inventors identified the varieties of tea listed in Claims 1 and 6 that have high levels of methylated catechins, and selected these teas for reducing triglyceride levels. Nothing in the prior art would lead one of ordinary skill in the art to select the presently claimed types of unfermented teas.

#### *Discussion of Independent Claim 1*

The Examiner alleges that Zeyuan teaches that certain teas may reduce blood triglyceride (BTG) levels. *Office Action* at page 4. The Examiner also contends Suzuki discloses that O-methylated catechin derivatives can be extracted from Benihomar cultivar (black tea). *See, Id.* Finally, the Examiner alleges that Iwasaki discloses “that catechins found in black tea are used in the healthy drink in an amount from 0.092 to 0.5g per 100 ml and thus it is predictable to provide for a black tea containing catechins in an amount from 0.092 to 0.5g per 100 ml in a healthy drink.” *Office Action* at page 5, emphasis added. Therefore, the Examiner contends that it would be obvious to one of skill in the art to begin with the tea disclosed in Zeyuan, substitute the Benihomar cultivar tea disclosed in Suzuki, and modify the amount of catechins disclosed in Iwasaki from 0.092 to 0.5g per 100 ml of catechins to the claimed 5 mg to 30 mg per 100 ml of the methylated catechins as recited in Claims 1. The Applicants respectfully traverse.

First, it is important to note than none of the cited references disclose that methylated catechins have any effect on BTG levels. The Examiner alleges that, “although the amount of catechins in the extract of Zeyuan *et al.* does not correlate with BTG reducing effects it would have been obvious to one skilled in the art that the black tea extract/functional beverage of

Zeyuan et al. and its constituents, such as the catechins are used for the method of reducing triglyceride levels in an individual.” *Office Action* at page 4. While it may be obvious that some component or combination of components in the beverage disclosed in Zeyuan has an effect on BTG levels, Zeyuan does not disclose higher levels of methylated catechins in particular have any effect on BTG levels. Indeed, the Examiner has admitted that “the amount of catechins in the extract of Zeyuan et al. does not correlate with BTG reducing effects.” *Id.* As addressed in Applicants’ Response to Office Action dated August 10, 2010, and admitted by the Examiner, Zeyuan does not disclose any correlation between methylated catechins and BTG reducing effects. Furthermore, Suzuki and Iwasaki do not disclose that any tea has any effect on BTG levels. Moreover, neither of the secondary references would suggest that methylated catechins have any BTG-reducing effects. In fact, the Suzuki reference discloses only black (i.e. fermented) tea, which has only insignificant quantities of methylated catechins.<sup>1</sup> Moreover, the Examiner’s allegation concerning the catechins disclosed in Iwasaki relate only to those catchins found in black tea used in the healthy drink. As discussed above, fermented teas, such as black teas, are known to contain only insignificant quantities of methylated catechins. Accordingly, none of the cited references disclose or suggest anything about the use of unfermented teas containing the recited levels of methylated catechins.

For at least this reason, Applicants respectfully submit that Claim 1, and all claims dependent therefrom, are nonobvious over the cited references.

Second, the cited references do not disclose a “functional beverage compris[ing] 5 mg to 30 mg/100 ml of at least one catechin selected from the group consisting of epigallocatechin-3-O-(3-O-methyl) gallate, epicatechin-3-O-(3-O-methyl) gallate, epigallocatechin-3-O-(4-O-methyl) gallate, gallicatechin-3-O-(3-O-methyl) gallate, catechin-3-O-(3-O-methyl) gallate, catechin-3-O-(4-O-methyl) gallate, gallicatechin-3-O-(4-O-methyl) gallate,” as recited in Claim 1. The Examiner contends that Iwasaki discloses catechins in a healthy drink in an amount from 0.092 to 0.5g per 100 ml and, thus, it is obvious to vary and/or optimize the amount of a compound provided in the composition according to the guidance provided by the reference to provide a composition with the desired properties. *Office Action* at page 5. However, Iwasaki discloses

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<sup>1</sup> Deeply fermented teas, such as black tea, contain little EGCG3”Me. Yamamoto et al., “The Change of Epigallocatechin-3-O-(3-O-methyl) gallate Content in Tea of Different Varieties, Tea Seasons of Crop and Processing Method,” in *Journal of the Japanese Society for Food Science and Technology*, 48:64-68 (2001).

“non-*epi*-catechins such as catechin, gallocatechin, catechin gallate and gallocatechin gallate and *epi*-catechins such as epicatechin, epigallocatechin, epicatechin gallate and epigallocatechin gallate.” *Iwasaki*, col. 2., ll. 32-36. *Iwasaki* does not disclose the use of the methylated catechins recited in Claim 1 in any quantity.

Furthermore, nothing in the cited art provides any indication that any level of methylated catechins achieves a BTG-lowering effect. It is well-recognized that “a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” *M.P.E.P.* § 2144.05 II.B. As discussed, there is nothing in *Iwasaki* or any other prior art reference that suggests that O-methylated catechins are responsible for the BTG-reducing effect. Therefore, discovering the “optimum or workable range” of O-methylated catechins cannot be “characterized as routine experimentation.” *See Id.* Furthermore, Zeyuan and Suzuki also do not disclose a functional beverage comprising “5 mg to 30 mg/100 ml” of the recited methylated catechins.

For at least this additional reason, Applicants respectfully submit that Claim 1, and all claims dependent therefrom, are nonobvious over the cited references.

Third, the cited references do not disclose “wherein said catechins are extracted from unfermented tea leaves of at least one selected from the group consisting of Benifuuki, Benifui, Benihomare, Yaeho, Yutakamidori, Okumusashi, Seishin-taipan, Seishin-oolong, Ohba-oolong, Benibana, Benihikari, Yamakai, Yamamidori, Karabeni, Koushun, Souhuu, Okumidori and mixtures thereof” as recited in Claim 1. (emphasis added). The Examiner contends Suzuki discloses that O-methylated catechin derivatives can be extracted from Benihomar cultivar (black tea). *Id.* However, amended Claim 1 recites that the tea must be unfermented, whereas the “Benihomare cultivar” of Suzuki is a type of black tea that is deeply fermented. As discussed above, such fermented teas have insignificant quantities of the recited methylated catechins. The unfermented tea leaves recited in Claim 1, including “Benihomare,” contain much greater quantities of O-methylated catechins such as EGCG3”Me than other varieties of tea. *Id.* at Table 3. Additionally, as demonstrated in the applicants’ Rule 132 Declaration, the O-methylated catechins such as EGCG3”Me contained in the recited types of unfermented tea provide a much greater BTG-reducing effect than other catechins disclosed in the cited references. Thus, not only

do none of the references disclose a functional beverage comprising “5 mg to 30 mg/100 ml” of the recited methylated catechins, none of these references provide any suggestion to do so.

For at least this further reason, Applicants respectfully submit that Claim 1, and all claims dependent therefrom, are nonobvious over the cited references.

For at least the reasons discussed above, the Applicants submits that Claim 1 is nonobvious over the cited references. Because Claims 2 and 5 depend directly from Claim 1, these claims are also nonobvious over the cited references. Thus, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

#### *Discussion of Independent Claim 6*

Claim 6 recites patentable distinctions similar to those discussed above in connection with Claim 1. For at least those reasons, Claim 6 is patentable over the cited references. Furthermore, Claim 6 is not “drawn to the method of reducing triglyceride levels in an individual by administering a functional beverage which may comprise other constituents, such as methylated catechins” as contested by the Examiner. *Office Action* at page 3 (emphasis added). Because Claim 7 depends directly from Claim 6, Claim 7 is also nonobvious over the cited references. Thus, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103(a).

#### *Discussion of Applicants' Rule 132 Declaration*

In Applicants' response filed August 10, 2010, the Applicants submitted a Rule 132 Declaration of Mari Yamamoto, one of the inventors of the present application. The Examiner indicated that the preparation of the test beverages 1 and 2 were not identical because it appeared that the test beverage 2 “Yabukita” tea leaves were not extracted at 90°C. Therefore, the Examiner argues that “the comparison between the two test beverages is not accurate and unexpected results are not established.” *Office Action* at page 2. Furthermore, the Examiner contends that the declaration does not include a comparison of any black teas.

Submitted herewith is an updated declaration of Mari Yamamoto showing that all three beverages were prepared under identical conditions and the tea leaves for all beverages were extracted at 90°C. (Declaration Attachment, paragraph 1, (a)-(c)). The data provided in the Declaration shows that Benifuuki tea (Test Beverage 1), which is one of the teas recited in present claims 1 and 6, contains a significant amount of catechins, including methylated catechins (6.8 mg/100 ml beverage), while Yabukita tea (Test Beverage 2), which is not recited in the

present claims, contains catechins, but no methyl catechins. In addition, the barley beverage (Test Beverage 3), which contains no detectable levels of catechins, whether methylated or not, was included as a control. (Declaration, paragraphs 6 and 8, and Tables 1 and 3).

As previously discussed, when the different beverages were tested for their ability to lower BTG levels, Test Beverage 1 exhibited a considerable reduction in BTG levels compared to both Test Beverage 2 (Yabukita green tea, which contains only low levels of methylated catechins) (Declaration, paragraph 9 and Table 4). Importantly, the average triglyceride level in the group of test subjects was significantly lowered after six weeks of consuming Test Beverage 1 (the Benifuki green tea containing the recited high levels of methylated catechins), whereas triglyceride levels in test subjects were not significantly lowered after six weeks of consuming the Test Beverage 2. Test Beverage 3 (barley tea, which contains no catechins of any kind) was also tested as a negative control. (*Id.*) These results illustrate that the beverages containing methylated catechins have remarkable and unobvious effects of reducing triglyceride levels compared to beverages not containing methylated catechins. In particular, the green tea beverage obtained from a strain of tea containing significant amounts of catechins, but no methyl catechins (Yabukita green tea), performed no better in reducing BTG than the barley tea, which has no catechins at all. Only the green tea beverage containing a significant level of methyl catechins had a significant effect on triglyceride levels. (Declaration, paragraph 10). Thus, because all beverages were prepared at an identical extraction temperature (90°C), the difference in reduction of BTG levels is clearly a result of the different amounts of methyl catechines, rather than any difference in extraction temperature.

The Examiner contends that the Declaration did not include a comparison of black teas. *Office Action* at page 2. As discussed above, Claims 1 and 6 are directed towards unfermented teas, not fermented black teas. Additionally, based on Applicants' disclosure one of skill in the art at the time of the invention would recognize that black tea containing only insignificant amounts of methylated catechins would achieve results similar to those obtained for the Yabukita green tea, which has similarly low levels of methylated catechins. Prior to the present invention, the compositions of green tea and black tea were believed to be substantially identical except green tea contains more catechins and black tea contains more flavonols. D. A. Balentaine *et al.*, *Crit. Rev. Food Sci. Nutr.*, 37:693, (1997). Furthermore, another study investigated the effect of the flavanol, theaflavin, and catechins on three patient groups: those given theaflavin purified from

black tea, those given theaflavin and catechins purified from black tea, and those given a placebo. Trautwein *et al.*, *Eur. J. Nutr.*, 49: 27–35, (2010). The study found no significant difference in reduction of BTG levels amongst patient groups. *Id.* Thus, one of skill in the art would assume that any BTG-reduction disclosed in Zeyuan was due to something other than theaflavin or catechins. Therefore, one of skill in the art would not expect a significant difference in reduction of BTG levels between black teas and Yabukita green tea (Test Beverage 2). Thus, beverages with high amounts of methyl catechines unexpectedly provide a superior reduction in BTG levels when compared to other beverages containing other types of catechins.

Nothing in the prior art would lead one having ordinary skill in the art to expect that methylated catechin-containing unfermented (green) tea would have such a superior result in lowering BTG compared to green tea lacking significant amounts of methylated catechins. These unexpected results are neither disclosed nor suggested by any of the cited references, either alone or in combination, could not have been predicted by one of ordinary skill in the art, and strongly support the nonobviousness of the present claims over the cited references. It is clear that in the absence of the inventors' own teachings, one having ordinary skill in the art would not have any reason to select the particular varieties of tea recited in the present claims out of all the many varieties of tea, or to select the recited methylated catechins at the recited levels, because such a person would not know to select the varieties that have high levels of methyl catechins, or that these compounds, at these levels, would have superior BTG reducing effects. It is only based on the disclosure of the present application that one of ordinary skill in the art would know to select specific varieties of tea, i.e. those with high levels of the recited methylated catechins at the recited levels, for the unexpected result of lowering BTG levels.

In view of the comments presented above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure,

including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

Applicants submit that all claims are in condition for allowance. Should there be any questions concerning this application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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